

Inventor : Cawthorne et al.
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REMARKS

This amendment is responsive to the Office Action mailed May 19, 2004 (hereinafter the "present Office Action"). Claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 are under examination in the present action. All claims stand rejected. Claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 have been amended in the present response. No pending claim has been canceled and no new claim has been added. Reconsideration of the present Office Action, entry of the aforementioned amended claims and allowance of the application are respectfully requested.

1. Applicants acknowledge the rejection of their request for continued examination (RCE) submitted January 30, 2004 as untimely. Applicants contend that the present request for continued examination (RCE) meets the requirements of 37 C.F.R. §1.114 since prosecution on the merits is closed due the finality of the present Office Action. In compliance with Rule 114, Applicants submit herewith a request for continued examination, an authorization for the payment of the requisite fee and a submission in the form of an information disclosure statement together with a reply to the present Office Action as required under 35 U.S.C. §132. Applicants respectfully request that the finality of the present Office Action be withdrawn pursuant to 37 C.F.R. §1.114 and that the instant submission be entered into the record.

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Applicants are grateful for the withdrawal of the rejections under 35 U.S.C. §112, second paragraph, 35 U.S.C. §102(b) and 35 U.S.C. §103(a), as detailed in the Office Action mailed July 30, 2003.

3-6. The rejection of claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5-8, 10-13 and 15 of U.S. Patent No. 6,004,928 has been maintained. Without conceding the correctness of this rejection and in an effort solely to advance the prosecution of the instant application, Applicants file concurrently herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321(c) wherein the Assignee of the present application, Société de Conseils de Recherches et d'Applications Scientifiques, S.A.S., waives and disclaims the terminal portion of the term of the entire patent to be granted upon the present application subsequent to the expiration date of U.S. Patent No. 6,004,928 and further agrees that any patent granted on present application shall be enforceable only for, and during such period, that it is commonly owned with U.S. Patent No. 6,004,928.

7 - 8. The rejection of claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 under 35 U.S.C. §103(a) as being unpatentable over WO96/35950 published in the name of Biomeasure, Inc. (hereinafter referred to as "WO'950") taken with Moller, et al., *Effects of the Somatostatin Analogue*

SMS 201-995 (sandostatin) on Mouth-to Caecum Transit Time and Absorption of Fat and Carbohydrates in Normal Man, (1988), Clinical Science, 75:345-50 (hereinafter referred to as "Moller") has been maintained. Applicants adopt their arguments with respect to the relevance of the cited references, i.e. WO'950 and Moller, as if realleged and recited herein, in their entirety, as presented in their submissions dated February 10, 2003 and January 30, 2004. Without conceding the correctness of this rejection, the Applicants have amended claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 to better distinguish the present invention, as claimed, from the prior art.

In particular, the claims of the present application require that the pharmaceutical compositions for the treatment of hyperlipidemia be comprised of an agonist which has: a). a greater selectivity for the somatostatin type-5 receptor, b). a higher binding affinity for the somatostatin type-5 receptor than for either of the somatostatin type-1, type-2, type-3 or type-4 receptors, and c). a binding affinity (K_i) of less than 5nM for the somatostatin type-5 receptor. As noted by the Examiner, the July 30, 2003 Office Action rejected the claims set for being directed to *SSTR-5 agonists*, not *SSTR-5 receptor selective agonists*. As correctly noted by the Examiner, WO'950 discloses somatostatin type-5 receptor agonists. As further noted by the Examiner, an SSTR-5 agonist is identified in the present application at page 9, line 29 to

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page 10, line 2, as a species of the somatostatin type-5 receptor selective agonists, as defined in the present application. In an effort to remove **SSTR-5 agonists**, as defined in the prior art, from the scope of claims of the present application, the Applicants have amended their claims to require that the somatostatin type-5 receptor selective agonists used in the claimed pharmaceuticals have a higher binding affinity (i.e., K_i) for SSTR-5 *than for either SSTR-1, SSTR-2, SSTR-3 or SSTR-4*. This amendment does not add new matter and is supported by the specification of the present application at page 9, lines 18 - 25. WO'950 defines an "SSTR-5 agonist" as only being more selective for SSTR-5 than for SSTR-2 and is silent as to a SSTR-5 agonist's ability to bind to the SSTR-1, SSTR-3 and SSTR-4 receptors. This new limitation to the claims is not found either in Moller, the secondary reference. To establish *prima facie* case of obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*,, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending there from is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicants contend that amended claims are not obvious based on WO'905.

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To further distinguish the present invention over the prior art, the claims have been amended to specifically exclude the teachings of the secondary reference, Moller, from the scope of the present application. It should be noted that Moller describes the action of a particular somatostatin analogue, SMS 201-995, in increasing mouth-to-caecum transit time, diminishing the rate of active monosaccharide absorption and lowering basal and postprandial triglyceride levels. As reported in Tables I and II of WO'950 on pages 4 and 7, respectively, SMS 201-995 has a K_i value greater than 5nM and is therefore excluded from the scope of the amended claims of the present application which require use of a somatostatin type-5 receptor selective agonist having a binding affinity (K_i) of **less than 5nM**. As such, Moller can not be combined with the teachings of primary reference, WO'950. Applicants contend that Moller, like WO'950, does not teach each and every limitation of the amended claims set, either alone or in combination with WO'950, and, therefore, does not support an obvious rejection under 35 U.S.C. §103(a)

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 32, 34, 35, 38, 40, 41, 44, 46, 47, 50, 52 and 53 under 35 U.S.C. §103(a) as being unpatentable over WO96/35950 taken with Moller, et al., *Effects of the Somatostatin Analogue SMS 201-995 (sandostatin) on Mouth-to Caecum Transit Time and Absorption*

of Fat and Carbohydrates in Normal Man, (1988), Clinical Science, 75:345-50.

9 - 10. Claims 34, 35, 40, 41, 46, 47, 52 and 53 stand rejected under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that the applicants regard as their invention. With respect to the rejection that the dependent claims lack the term "selective," without conceding the correctness of this rejection and in an effort solely to put this application in a condition for allowance, dependent claims 32, 38, 44 and 50 have been amended to be consistent with the independent claims, as suggested by the Examiner. AS for the Examiner's rejection of the claims for the placement of the phrase "selective for somatostatin type-5 receptors," without conceding the correctness of this rejection and in an effort solely to put this application in a condition agreeable to the Examiner, claims 34, 35, 40, 41, 46, 47, 52 and 53 have been amended to move the offending phrase, "selective for somatostatin type-5 receptors" from before "agonist" to after "agonist," as suggested by the Examiner.

Applicants contend that the aforementioned amendments overcome the rejection of claims 34, 35, 40, 41, 46, 47, 52 and 53 under 35 U.S.C. §112, second paragraph, and respectfully request reconsideration and withdrawal of said rejection.

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In summary, it is believed that the instant application is now in an allowable condition and such allowance is earnestly solicited.

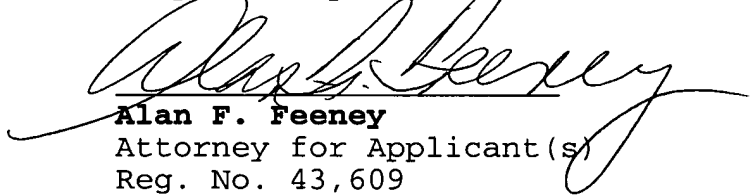
Examiner Mohamed is invited to telephone the Applicant's representative at the telephone number indicated below to facilitate the prosecution of this application. The Commissioner is hereby authorized to charge any additional fees deemed necessary to Deposit Account 50-0590.

Date:

11/22/2004

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Respectfully submitted,


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